Appl. No. 10/572,782

Amdt. Dated June 30, 2009

Reply to Office action of March 30, 2009

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

- 1. (Currently amended) A stable phosphatidylserine (PS) composition of matter comprising from about 1 to about 99% (w/w) phosphatidylserine, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months.
- 2. (Currently amended) The composition of matter of claim 1, comprising from about 1 to about 99% (w/w) phosphatidylserine, from about 1 to about 99% (w/w) phosphatidy1choline (PC), preferably from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w), Comega-3 source, from about 1 to about 99% (w/w) Omega-6 polyunsaturated fatty acids source, and/or from about 1 to about 99% 1 to about 99% (w/w) sterol or sterol esters.
- 3. (Currently amended) The composition of matter of claim 1, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months. preferably at least 12 months. more preferably at least 24 months.
- 4. (Currently amended) The composition of matter of claim 1, characterized in being substantially devoid of phospholipase activity, particularly phospholipase D activity.
- 5. (Previously presented) The phosphatidylserine composition of matter of claim 1, being in powder form.

Appl. No. 10/572,782 Amdt. Dated June 30, 2009

Reply to Office action of March 30, 2009

- 6. (Currently amended) The phosphatidylserine composition of matter of claim 1, wherein the phosphatidylserine is present in the form of a salt which is substantially soluble in organic solvents, preferably the sodium salt.
- 7. (Currently amended) The phosphatidylserine composition of matter of claim 6, wherein said PS sodium salt is obtained by treatment of a PS divalent salt with a metal chelator, preferably EDTA.
- 8. (Currently amended) The phosphatidylserine composition of matter of claim 1, wherein the phosphatidylserine is present in the form of a salt which is substantially non-soluble in organic solvents, preferably the calcium salt.
- 9. (Currently amended) A stable liquid preparation of phosphatidylserine comprising from about 1 to about 99% (w/w) phosphatidylserine, in the form of a soluble salt, from about 1 to about 99% (w/w) other functional ingredients, from about 1 to about 99% (w/w) phosphatidy1choline (PC), preferably from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w) phosphatidylinositol (PI), from about 1 to about 99% (w/w) Omega-3 source, from about 1 to about 99% (w/w) Omega-6 polyunsaturated fatty acids source, and/or from about 1 to about 99% 1 to about 99% (w/w) sterol or sterol esters dissolved in oil, preferably a medium-chain triglyceride, and wherein no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months.
- 10. (Currently amended) The liquid phosphatidylserine preparation of claim 9, comprising from about 1 to about 90% (w/w) phosphatidylserine, preferably from about 2.5 to about 55% (w/w).
- 11. (Currently amended) The composition of matter of claim 9, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a

Appl. No. 10/572,782 Amdt. Dated June 30, 2009 Reply to Office action of March 30, 2009

storage period of at least 6 months, preferably at least 12 months, more preferably at least 24 months.

- 12. (Currently amended) The liquid phosphatidylserine preparation of claim 9, further comprising additional bio-functional ingredient/s which may be preferably at least one of lecithin, phospholipids, vitamins, anti-oxidants, minerals, nutritional proteins or peptides, sterol and other derivatives, nutritional carbohydrates and their derivatives, amino acids, plant extracts, fermentation products, glyceride derivatives (mono- and diglycerides), poly-unsaturated fatty acids, and Omega-3 and/or Omega-6 lipids.
- 13. (Currently amended) A stable dispersion of phosphatidylserine comprising a stable phosphatidylserine (PS) composition of matter comprising from about 1 to about 99% (w/w) phosphatidylserine in the form of an insoluble salt, from about 1 to about 99% (w/w) other functional ingredients, from about 1 to about 99% (w/w) phosphatidylcholine (PC), preferably from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w) phosphatidylinositol (PI), from about 1 to about 99% (w/w) Omega 3 source, from about 1 to about 99% (w/w) Omega 6-polyunsaturated fatty acids source, and/or from about 1 to about 99% 1 to about 99% (w/w) sterol or sterol esters, dispersed in a liquid base, preferably a lipid base, more preferably an oil base, and wherein no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months.
- 14. (Currently amended) The phosphatidylserine dispersion of claim 13, comprising from about 1 to about 70% (w/w) phosphatidylserine, preferably from about 5% to 45% (w/w).
- 15. (Currently amended) The phosphatidylserine dispersion of claim 13, wherein said oil base is a triglyceride base, particularly medium chain triglyceride base or vegetable oil.

- 16. (Currently amended) The phosphatidylserine dispersion of claim 13, further comprising additional bio-functional ingredient/s, preferably which may be at least one of lecithin, phospholipids, vitamins, anti-oxidants, minerals, nutritional proteins or peptides, sterols and other derivatives, nutritional carbohydrates and their derivatives, amino acids, plant extracts, fermentation products, glyceride derivatives (mono- and diglycerides), poly-unsaturated fatty acids, and Omega-3 and/or Omega-6 lipids.
- 17. (Previously presented) The phosphatidylserine dispersion of claim 13, characterized in that said dispersion is solid at room temperature and fluid at elevated temperatures, and it is suitable for softgel encapsulation.
- 18. (Currently amended) The dispersion of phosphatidylserine composition of matter of claim 13, for use as a dietary supplement, nutraceutical food and/or drug additive.
- 19. (Previously presented) The phosphatidylserine liquid preparation of claim 9, for use as a dietary supplement, nutraceutical food and/or drug additive.
- 20. (Previously presented) The phosphatidylserine dispersion of claim 13, for use as a dietary supplement, nutraceutical food and/or drug additive.
- 21. (Previously presented) A food article comprising one of a phosphatidylserine composition of matter, wherein said composition of matter may be in powder form, a stable liquid preparation of phosphatidylserine dispersed in a lipid base, or a stable dispersion of phosphatidylserine dispersed in a lipid base, wherein said composition comprises from about 1 to about 99% (w/w) phosphatidylserine, from about 1 to about 1 to about 99% (w/w) phosphatidylcholine (PC), preferably from about 1 to about 99% (w/w) phosphatidylcholine (PE), from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w) phosphatidylinositol (PI), from about 1 to about 99% (w/w) Omega-6 polyunsaturated fatty acids essurce, and/or from about 1 to about 99%

Appl. No. 10/572,782

Amdt. Dated June 30, 2009

Reply to Office action of March 30, 2009

1 to about 99% (w/w) sterol or sterol esters, and optionally further comprising at least one additional active ingredient, which may be one of lecithin, phospholipids, vitamins, anti-oxidants, minerals, sterol, nutritional carbohydrates, amino acids and polyunsaturated fatty acids, and wherein no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months.

22. (Currently amended) The composition of matter food article of claim 21, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months, preferably at least 12 months, more preferably at least 24 months.

23. (Cancelled)

24. (Currently amended) A pharmaceutical composition comprising one of a phosphatidylserine composition of matter, wherein said composition of matter may be in powder form, a stable liquid preparation of phosphatidylserine dispersed in a lipid base, or a stable dispersion of phosphatidylserine dispersed in a lipid base, wherein said composition comprises from about 1 to about 99% (w/w) phosphatidylserine, from about 1-to about 99% (w/w) other functional ingredients, from about 1 to about 99% (w/w) phosphatidy1choline (PC), preferably from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w) phosphatidylinositol (PI), from about 1 to about 99% (w/w) Omega-3 source, from about 1 to about 99% (w/w) Omega-6-polyunsaturated fatty acids source, and/or from about 1 to about 99% 1 to about 99% (w/w) sterol or sterol esters, and optionally further comprising at least one additional biofunctional ingredient, which may be one of lecithin, phospholipids, vitamins, anti-oxidants, minerals, sterols, nutritional carbohydrates, amino acids and poly-unsaturated fatty acids and/or at least one pharmaceutically acceptable additive, diluent, carrier or excipient, and wherein no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months.

Appl. No. 10/572,782 Amdt. Dated June 30, 2009 Reply to Office action of March 30, 2009

25. (Currently amended) The composition of matter of claim 21, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months, preferably at least 12 months, more preferably at least 24 months.

26. (Cancelled)

- 27. (Currently amended) A capsule containing one of a phosphatidylserine composition of matter, wherein said composition of matter may be in powder form, a stable liquid preparation of phosphatidylserine dispersed in a lipid base, or a stable dispersion of phosphatidylserine dispersed in a lipid base, wherein said composition comprises from about 1 to about 99% (w/w) phosphatidylserine, from about 1 to about 1 to about 99% (w/w) phosphatidylcholine (PC), preferably from about 1 to about 99% (w/w) phosphatidylcholine (PE), from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w) phosphatidylinositol (PI), from about 1 to about 99% (w/w) Omega 6 polyunsaturated fatty acids source, and/or from about 1 to about 99% 1 to about 99% (w/w) sterol or sterol esters, wherein said capsule is preferably a soft gelatin capsule, and wherein no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months.
- 28. (Currently amended) The composition of matter of claim 27, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 6 months, preferably at least 12 months, more preferably at least 24 months.

29. (Cancelled)

Appl. No. 10/572,782 Amdt. Dated June 30, 2009 Reply to Office action of March 30, 2009

- 30. (Previously presented) The phosphatidylserine composition of matter of claim 2, for use as an enhancer of cognitive performance and learning ability.
- 31. (Previously presented) The phosphatidylserine preparation of claim 9, for use as an enhancer of cognitive performance and learning ability.
- 32. (Previously presented) The phosphatidylserine dispersion of claim 13, for use as an enhancer of cognitive performance and learning ability.
- 33. (Currently amended) The phosphatidylserine composition of matter of claim 2, for use in <u>improving preventing memory loss</u>, particularly age-related memory loss.
- 34. (Currently amended) The phosphatidylserine composition of matter of claim 9, for use in <u>improving preventing memory loss</u>, particularly age-related memory loss.
- 35. (Currently amended) The phosphatidylserine composition of matter of claim 13, for use in <u>improving preventing memory loss</u>, particularly age-related memory loss.
- 36. (Original) A process for the preparation of a stable phosphatidylserine composition of matter, comprising the steps of:
- a. incubating an aqueous mixture of L-serine and optionally appropriate orgamous solvents with lecithin in the presence of an immobilized phospholipase D for a suitable period of time to give phosphatidylserine;
- b. removing the upper layer which contains the phosphatidylserine;
- c. obtaining the phosphatidylserine from the upper layer by standard means;
- d. washing the resulting phosphatidylserine with an appropriate aqueous solution to remove excess L-serine;
- e. optionally washing the phosphatidylserine obtained in step (d) with a suitable organic solvent, preferably ethanol at an elevated temperature; and
- f. drying the phosphatidylserine obtained in step (e).

Pule 1.126

Appl. No. 10/572,782 Amdt. Dated June 30, 2009 Reply to Office action of March 30, 2009

- 37. (Original) The process of claim 36, further comprising the step of deactivating any residual phospholipase activity in the obtained phosphatidylserine by suitable means.
- 38. (Previously presented) The process of claim 36, wherein said phospholipase is immobilized on an insoluble matrix and is optionally surfactant coated, and after step (a), the reaction mixture is allowed to stand until the phospholipase D precipitates.
- 39. (Currently amended) A process for preparing a stable phosphatidylserine oil-based liquid preparation of phosphatidylserine comprising the step of dissolving a stable phosphatidylserine (PS) composition of matter, said composition of matter comprising from about 1 to about 99% (w/w) phosphatidylserine, from about 1 to about 99% (w/w) phosphatidylcholine (PC), preferably from about 1 to about 99% (w/w) phosphatidylcholine (PE), from about 1 to about 99% (w/w) phosphatidylethanolamine (PE), from about 1 to about 99% (w/w) phosphatidylinositol (PI), from about 1 to about 99% (w/w) Omega 3 source, from about 1 to about 99% (w/w) Omega 6 source polyunsaturated fatty acids, and/or from about 1 to about 99% 1 to about 99% (w/w) sterol or sterol esters, in a suitable oil base, preferably a medium-chain triglycerides or vegetable oil.

40.

A1. (Cancelled)

42. (Original) A stable phosphatidylserine composition of matter which is resistant to degradation by at least one of the following routes: enzymatic hydrolysis and transphosphatidylation, partial or full hydrolysis of the phospholipid fatty acids, removal of the phosphate group, decarboxylation of L-serine carboxylate group, phospholipids hydroperoxidation, oxidation of the primary amine group of the L-Serine head-group.

Rule 1.126

Appl. No. 10/572,782 Amdt. Dated June 30, 2009 Reply to Office action of March 30, 2009

42.

- 43. (Original) A stable liquid phosphatidylserine preparation, which is resistant to degradation by at least one of the following routes: enzymatic hydrolysis and transphosphatidylation, partial or full hydrolysis of the phospholipids fatty acids, removal of the phosphate group, decarboxylation of L-serine carboxylate group, phospholipids hydroperoxidation, oxidation of the primary amine group of the L-Serine head-group.
- 44. (Original) A stable dispersion of phosphatidylserine, which is resistant to degradation by at least one of the following routes: enzymatic hydrolysis and transphosphatidylation, partial or full hydrolysis of the phospholipids fatty acids, removal of the phosphate group, decarboxylation of L-serine carboxylate group, phospholipids hydroperoxidation, oxidation of the primary amine group of the L-Serine head-group.
- 45. (New) The composition of matter of claim 1, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 24 months.
- 45. 46. (New) The composition of matter of claim 9, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 24 months.
- 4. (New) The dispersion of phosphatidylserine of claim 13, wherein no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 12 months.
- 47. (New) The dispersion of phosphatidylserine of claim 13, wherein no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 24 months.

Ricle 1.126

Appl. No. 10/572,782 Amdt. Dated June 30, 2009 Reply to Office action of March 30, 2009

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- 49. (New) The food article of claim 21, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 24 months.
- 50. (New) The capsule of claim 27, characterized in that no more than about 1 to about 5% of the phosphatidylserine are decomposed after a storage period of at least 24 months.
- 50. (New) The liquid phosphatidylserine preparation of claim 9, comprising from about 2.5 to about 55% (w/w).
- 51. 52. (New) The phosphatidylserine dispersion of claim 13, comprising from about 5% to 45% (w/w).